Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D2118813	05/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Central Medical Associates	1321 Ring Road, Ste #105, Elizabethtown, KY	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual, review of proficiency testing results from the Medical Laboratory Evaluation (MLE) proficiency testing agency, and staff interview on 05/17/2019, the laboratory failed to ensure proficiency testing samples were tested by all testing personnel who routinely perform patient testing for testing events 2018 MLE-M1, 2018 MLE-M2, 2018 MLE-M3, and 2019 MLE-M1. Findings include: 1. Review of the policy and procedure manual revealed the Proficiency Testing Procedure stated "All testing personnel are to be rotated and take turns testing PT samples." 2. There was no evidence of Testing Personnel #2 listed on the CMS Form 209 testing proficiency samples for three testing events in 2018 and the first testing event in 2019. 3. Testing personnel acknowledged in an interview at 10:00 AM on 05/17/2019, the laboratory failed to have a system to ensure established policy was followed and proficiency testing samples were rotated among all testing personnel responsible for patient testing.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed

	when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing results from Medical Laboratory Evaluation (MLE), review of policy and procedure manual, and staff interview on 05/17/2019, it was determined the laboratory director failed to follow the facility's Proficiency Testing Procedure and ensure the corrective action plan was followed when analytes were found to be unacceptable or unsatisfactory. Findings include: 1. Review of the facility's policy and procedure manual revealed policy entitled Proficiency Testing Procedure stated "After grades are received, complete a Proficiency Testing QA Review and retain with PT records. This review must include a plan of corrective action, if indicated, and should be signed by the Laboratory Director (or designee) and by the testing staff." 2. Review of proficiency testing results from MLE revealed the laboratory received an unsatisfactory score of 0 percent for the High Sensitive C-Reactive Protein analyte in the 2018 MLE-M2 testing event. There was no evidence of review of results by the Laboratory Director or staff. There was no evidence of corrective action performed. 3. Testing Personnel acknowledged in an interview at 10: 00 AM on 05/17/2019, the laboratory failed to have a system in place to ensure policy was followed and corrective action was performed, documented, and reviewed and signed by the Laboratory Director or testing staff when testing analytes were found to be unsatisfactory.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of quality control results on the Access chemistry analyzer and staff interview on 05/17/2019, the Technical Consultant failed to ensure the analyzer was functioning properly prior to patient testing on days of 04/16/2019, 04/17/2019, 04/18 /2019, and 04/19/2019. Findings include: 1. Record review failed to reveal quality control results for Total Testosterone from 04/16/2019 thru 04/19/2019. Record review revealed twenty (20) patient results were reported. 2. Record review failed to reveal quality control results for Total Prostate Specific Antigen from 04/16/thru 04/19 /2019. Record review revealed twenty (20) patient results were reported. 3. Record review failed to reveal quality control results for Free Thyroxine from 04/16/2019 thru 04/19/2019. Record review revealed eighty-six (86) patient results were reported. 4. Record review failed to reveal quality control results for Thyroid Stimulating Hormone from 04/16/2019 thru 04/19/2019. Record review revealed one hundred and nine (109) patient results were reported. 5. The Technical Consultant acknowledged in an interview at 12:30 PM on 05/17/2019, the laboratory failed to have a policy in place to outline steps for the treatment of patient samples when quality control results were not available and the laboratory analyzers failed to function properly.